40 CFR Parts 796 and 798

[OPTS-46104B; FRL-3572-1]

Toxic Substances Control Act Test Guidelines; Technical Amendments

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Final rule; technical

amendments.

SUMMARY: This document reinstates in the Code of Federal Regulations various changes that were inadvertently omitted from toxic substances test guidelines published in the Federal Register of September 27, 1985 (40 FR 39252), but which were carried in the Code of Federal Regulations (CFR) for 1986 and 1987 and were removed by an Office of the Federal Register (OFR) correction published in the Federal Register of December 20, 1988 (53 FR 51099). As this document merely reinstates amendments to guidelines that impose no regulatory burden, advance notice and public comment are unnecessary and this document becomes effective on publication.

EFFECTIVE DATE: May 16, 1989.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In the Federal Register of September 27, 1985 (50 FR 39252), EPA added toxic substances test guidelines in 40 CFR Parts 796, 797, and 798. The document EPA submitted to OFR for publication inadvertently omitted changes in 40 CFR Parts 796 and 798 that were made during the numerous in-house revision cycles. These changes were not made in the final rule published in the Federal Register, but were apparently nevertheless incorporated in the Code of Federal Regulations (CFR) issued in 1986. Therefore, there are discrepancies between the toxic substances test guidelines in 40 CFR Parts 796 and 798 published in the Federal Register of September 27, 1985, and those codified in the CFR's of 1986 and 1987.

As the original September 27, 1985 daily issue publication is the controlling version, OFR issued a correction document, published in the Federal Register of December 20, 1988 (53 FR 51099), that conforms the CFR to the September 27, 1985 Federal Register final rule. EPA is issuing these technical amendments to 40 CFR Parts 796 and 798 because most of the changes that were inadvertently omitted from the Federal Register final rule of September 27, 1985 were intended and should be reinstated in the CFR.

Codification of these technical amendments to guidelines does not impose any regulatory obligation on any person who may be subject to the Toxic Substances Control Act (TSCA) section 4 test rule. Specific guidelines do not become mandatory test standards until they are promulgated as such in individual section 4 rulemakings. When

promulgated in such test rules, the pertinent TSCA guidelines become test standards for only that particular section 4 rule and do not serve as generic test standards. EPA may propose modifications to the various guidelines as they are utilized for chemical-specific test rules. In each chemical-specific rule, the proposed test standards and any modification will be subject to public comment.

List of Subjects in 40 CFR Parts 796 and 798

Testing, Environmental protection, Chemical fate, Environmental effects, Chemicals.

Dated: May 8, 1989.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 796-[AMENDED]

- 1. In Part 796:
- a. The authority citation for Part 796 continues to read as follows:

Authority: 15 U.S.C. 2603.

§ 796.3140 [Amended]

b. In § 796.3140 Anaerobic biodegradability of organic chemicals, in paragraph (b)(2)(i)(C) in the first sentence add "are" after "components" and before "added."

PART 798—[AMENDED]

- 2. In Part 798:
- a. The authority citation for Part 798 continues to read as follows:

Authority: 15 U.S.C. 2603.

§ 798.1150 [Amended]

b. In § 798.1150 Acute inhalation toxicity, in paragraph (f)(8) change "food" to "feed" in the two places it appears.

§ 798.1175 [Amended]

c. In § 798.1175 Acute oral toxicity, in paragraphs (f)(6) (ii) and (iii) change "food" to "feed."

§ 798.2250 [Amended]

d. In § 798.2250 Dermal toxicity, in paragraphs (e)(9)(v) and (f)(3)(ii)(D) change "food" to "feed."

§ 738.2450 [Amended]

e. In § 798.2450 Inhalation toxicity, in paragraph (d)(9) in the two places it appears, in paragraph (d)(10)(v), and in paragraph (e)(3)(iv)(D), change "food" to "feed"; and in paragraph (d)(11)(ii)(B) change the phrase "expected or

observed toxicity" to "expected and/or observed toxicity."

§ 798.2650 [Amended]

f. In § 798.2650 Oral toxicity, in paragraphs (e)(8)(v) and (f)(3)(ii)(D) change "food" to "feed"; in paragraph (e)(10)(iii) delete the period at the end of the paragraph and add "; and (rodent-zymbal glands)."

§ 798.2675 [Amended]

g. In § 798.2675 Oral toxicity with satellite reproduction and fertility study, in paragraphs (e)(8)(v) and (f)(3)(ii)(D), change "food" to "feed" and in paragraph (e)(9)(ii)(B) change the phrase "expect or observed activity" to "expected and/or observed activity."

§ 798.3260 [Amended]

h. In \$ 798.3260 Chronic toxicity, in paragraph (b)(6)(iii)(C), in paragraph (b)(7)(vi) in the two places it appears, and in paragraph (c)(3)(i)(B)(4) change "food" to "feed."

§ 798.3300 [Amended]

i. In § 798.3300 Oncogenicity, in paragraph (b)(6)(iii)(C), in paragraph (b)(7)(v) in the two places it appears, and in paragraph (c)(3)(i)(B)(4) change "food" to "feed"; also, make the following correction: In paragraph (d)(8) add "of" after "Journal."

§ 798.3320 [Amended]

j. In § 798.3320 Combined chronic toxicity/oncogenicity, in paragraphs (b)(6)(iii)(C), in paragraph (b)(7)(v) in the two places it appears, and in paragraph (c)(3)(i)(B)(4), change "food" to "feed"; and in paragraph (b)(6)(iii)(A) in the first sentence insert "to" after "per hour," and before "ensure."

§ 798.4350 [Amended]

k. In § 798.4350 Inhalation developmental toxicity study, in paragraph (f)(3)(iii)(E) change "food" to "feed."

§ 793.7100 [Amended]

- 1. In § 798.7100 Metabolism:
- i. In paragraph (c)(1)(i) in the next-tolast sentence, change "in several species" to "in more than one species";
- ii. In paragraph (c)(2)(ii), change "noeffect-level" to "no-observable-effect level";
- iii. In paragraph (c)(2)(iv), change "single or repeated doses" to "single and repeated doses":
- iv. In paragraphs (c)(3) and (c)(5)(iii), change "95 percent" to "90 percent";
- v. In paragraphs (c)(5)(iii) and (c)(5)(iv)(A), change "i.e.," to "e.g.,";
- vi. In paragraph (c)(5)(iv)(A), in the first sentence remove "1.5" and delete

the last sentence, "In the dog, quantities of label in urine and feces should be measured at appropriate intervals (i.e., every 6 hours for the first 48 hours after dosing and every 12 hours for the remaining 5 days) throughout the study for all animals."; and

vii. In paragraph (c), the words "the rat and dog" are deleted and the words "those employed may" are added in their place.

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